



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,412	01/22/2001	Ruowen Ge	1781-0215P	7335

2292 7590 02/20/2004

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

MOHAMED, ABDEL A

ART UNIT	PAPER NUMBER
----------	--------------

1653

DATE MAILED: 02/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

5

Office Action Summary

Application No.

09/766,412

Applicant(s)

GE ET AL.

Examiner

Abdel A. Mohamed

Art Unit

1653

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13-16, 19, 20, 22, 23 and 25-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-10, 13-16, 19, 20, 22, 23 and 25-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

ACKNOWLEDGMENT OF RESPONSE TO ELECTION OF RESTRICTION

REQUIREMENT AND THE STATUS OF THE CLAIMS

1. Applicant's remarks with respect to election of the restriction requirement filed 9/25/03 is acknowledged, considered and entered. In view of Applicant's request claims 1, 9, 10, 15, 22 and 23 have been amended, claims 11, 12, 17, 18, 21 and 24 have been canceled and claims 25-28 have been added. Thus, claims 1-10, 13-16, 19, 20, 22, 23 and 25-28 are now pending in the application. It is noted that Applicant has elected with traverse Group I (previous claims 1-18) along SEQ ID NO:30. However, Applicant has regrouped the method for preventing or treating undesired angiogenesis (Group II; previous claims 19-21) and method for preventing or treating primary tumor growth or metastasis of Group III (previous claims 22-24) along with the peptide of Group I (previous claims 1-18) by amending the claims to read as methods for preventing or treating primary tumor growth or metastasis by preventing undesired angiogenesis by administering the compound of Group I. As such, the method of treating tumor growth appears to be a species of the method for preventing undesired angiogenesis. Further, Applicant asserts that it would not be unduly burdensome on the Examiner to examine the related sequences along with the sequence of SEQ ID NO:30. Contrary to Applicant's assertion, the sequences are patentably distinct because they are unrelated sequences and each unrelated sequence is considered a separate and distinct product, therefore, a further restriction is applied to each sequences. Thus, all SEQ ID NO's other than SEQ ID NO:30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected invention, there being no allowable generic or linking claim. Hence, the previous election/restriction has been

Art Unit: 1653

modified on the merits of pending claims 1-8, 13, 14, 19, 22 and 25-28, as they read on elected SEQ ID NO:30, follows.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-8, 13, 14, 19, 22 and 25-28, drawn to plasminogen, pharmaceutical composition thereof and to a method for preventing or treating primary tumor growth or metastasis by preventing undesired angiogenesis, classified in classes 530 and 514, subclasses 380, 326, 2 and 13, respectively.
 - II. Claims 1-8, 13, 14, 19, 22 and 25-28, drawn to endostatin, pharmaceutical composition thereof and to a method for preventing or treating primary tumor growth or metastasis by preventing undesired angiogenesis, classified in classes 530 and 514, subclasses 311, 356, 326 and 13, respectively.
 - III. Claims 1-8, 13, 14, 19, 22 and 25-28, drawn to vascular endothelial growth factor (VEGF), pharmaceutical composition thereof and to a method for preventing or treating primary tumor growth or metastasis by preventing undesired angiogenesis, classified in classes 530 and 514, subclasses 326, 399 and 13, respectively.
 - IV. Claims 1-8, 13, 14, 19, 22 and 25-28, drawn to KDR/FLK-1 receptor protein, pharmaceutical composition thereof and to a method for preventing or treating

primary tumor growth or metastasis by preventing undesired angiogenesis,
classified in classes 530 and 514, subclasses 326, 324 and 13, respectively.

The inventions are distinct, each from the other because of the following reasons:

3. Inventions I, II or III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different sources, different preparations, different structures, different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are related as independent compounds/compositions, which are not connected in design, operation or effect. Although, the compositions/compounds of Groups I-IV are used as pharmaceutical formulations for the same method of preventing or treating primary tumor growth or metastasis by preventing undesired angiogenesis, however, the compositions/compounds have different sources, structures resulting in different functions and different effect. The groups require different patent and literature search, and a reference teaching the use of plasminogen which is a plasma glycoprotein synthesized in the liver (See e.g. page 1, last paragraph in the instant specification) as claimed in Group I will not teach Groups II-IV proteins. Further, the proteins of Groups II-IV, each differs in source and structure, wherein the endostatin protein of Group II is identified from a hemangioendothelioma cell line having a 20 kDa C-terminal fragment of collagen XVIII (See e.g., page 2, lines 21-25 in the instant specification), Group III VEGF protein is a potent endothelial specific mitogen (See page 3, lines 1-3 in the instant specification) and Group IV KDR/FLK-1 receptor proteins are expressed in endothelial cells and stimulate endothelial cell proliferation and migration (See e.g., page 2, lines 5-8 in the instant specification). Thus, the

Art Unit: 1653

compounds/compositions as grouped are independent and distinct inventions, which differ, in material make up and composition requiring different reaction conditions. Hence, one does not require the other for ultimate use and as such is capable of separate manufacture, use and sale, and is novel and patentable over each other.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because the searches for individual subject sets are not coextensive, restriction for examination purposes as indicated is proper.

5. A telephone call was made to Richard Gallagher on 2/9/04 to request an oral election to the above restriction requirement, but did not result in an election being made.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

CONCLUSION AND FUTURE CORRESPONDENCE

8. Claims 1-10, 13-16, 19, 20, 22, 23 and 25-28 are subject to restriction or election requirement.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

 Mohamed/AAM

February 9, 2004